



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

JUL 9 2002

ANADA 200-253

Robert D. Gunderson
Vice President Regulatory Affairs
Phoenix Scientific Inc.
3915 South 48th St Terrace
P.O. Box 6457
St Joseph, MO 64506

Dear Mr. Gunderson,

This is in reference to your Drug Experience Report dated February 20, 2001 (submission date in error), which was received by the Center for Veterinary Medicine on February 27, 2002, concerning Prostamate™ (dinoprost tromethamine), ANADA 200-253. The submission includes clinical data and promotional pieces for Phoenix Scientific and for your distributor [redacted].

The Prostamate™ promotional pieces are determined to be labeling under 21 CFR 202.1(l)(2). We note that the flyer from Phoenix provides adequate information for use, dosage and other benefits, yet it fails to provide risk information relating to side effects, warnings, and precautions in the body of the text in the same language and emphasis as it is provided in the approved labeling (21 CFR 201.105(d)(1)).

We request that you discontinue using this promotional item immediately and revise the future materials to include all required information. We request that you give due consideration and attention to your company's promotional practices and ensure that your promotional materials comply with the requirements of 21 CFR 201.105(d)(1).

Incidentally, we also noted a typographical error within the other promotional piece in this submission, the circular from [redacted]. The *Warning* paragraph repeats the phrase "*persons with bronchial and other respiratory problems should exercise extreme caution when handling this*". This error causes the paragraph to be potentially confusing to users of your product.

Please inform us of your intentions as soon as possible or in any event within 30 days of the receipt of this letter. If you have any questions, you may contact us at (301) 827-6642.

Sincerely yours,

[Signature]
Mohammad I. Sharar, D.V.M., M.Sc.
Team Leader, Marketed Product Scientific
and Regulatory Review Team II, HFV-216
Division of Surveillance
Center for Veterinary Medicine